

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

In re INTUNIV ANTITRUST
LITIGATION

This Document Relates to *Indirect
Purchaser Actions*

REQUEST FOR ORAL ARGUMENT
Lead Case No. 1:16-cv-12396-ADB

**SHIRE’S MOTION TO DISMISS INDIRECT PURCHASER PLAINTIFFS’
CONSOLIDATED AND AMENDED COMPLAINT**

Pursuant to Federal Rule of Civil Procedure 12(b)(6), the defendants Shire LLC and Shire U.S., Inc. (collectively “Shire”), move to dismiss the Consolidated and Amended Class Action Complaint (“Complaint”) filed by Indirect Purchaser Plaintiffs Tina Picone, Carmen Richard, Shana Wright, and Sherry Cummisford (“Plaintiffs”) for failure to state a claim upon which relief can be granted. The grounds for Shire’s motion are set forth in detail in Shire’s supporting Memorandum of Law and the Declaration of Joshua Barlow (both of which are filed herewith) and may be summarized as follows:

1. This putative class action arises out of the litigation and settlement of patent matters related to Shire’s attention deficit hyperactivity (“ADHD”) medication, Intuniv[®]. Shire initiated patent infringement actions against a number of manufacturers which sought approval to market and sell generic forms of Intuniv. It subsequently settled those matters with those manufacturers, including defendant Actavis¹ as well as non-parties

¹ In the Complaint, the term “Actavis” collectively refers to Actavis Elizabeth LLC and Actavis Holdco U.S., Inc. Compl. p. 1.

TWi Pharmaceuticals, Inc. (“TWi”) and Anchen Pharmaceuticals, Inc. (“Anchen”) (collectively “TWi/Anchen”).²

2. Plaintiffs are consumer purchasers of Intuniv who allege that Shire engaged in anticompetitive or otherwise unlawful conduct in connection with its infringement claims and settlements, which, in turn, delayed entry of generic Intuniv into the marketplace for approximately two years. Specifically, Plaintiffs allege (i) that some of Shire’s patent infringement claims were a “sham,” and (ii) that Shire settled its patent claims by entering into separate anticompetitive “reverse payment” settlements with Actavis and TWi/Anchen.
3. On the basis of these allegations, Plaintiffs assert 25 causes of action against Shire under the laws of five different states: Massachusetts, Florida, Missouri, New York, and Wisconsin.³ Twenty of Plaintiffs’ causes of action are based on alleged violations of the Sherman Act, 15 U.S.C. §§ 1 and 2. The remaining five assert stand-alone claims for “unfair” or “deceptive” conduct in violation of state law. None has merit.
4. Plaintiffs’ allegations do not state a plausible claim for relief, and the Court should dismiss their Complaint for the following reasons:

² Plaintiffs do not make clear in their complaint whether they are actually challenging the TWi/Anchen settlement (compare ¶ 1 with ¶¶ 84, 106), but for purposes of this motion, Shire assumes that they are.

³ Mass. Gen. Laws ch. 93A *et seq.*; the Florida Deceptive and Unfair Trade Practices Act (“FDUTPA”), Fla. Stat. § 501.201, *et seq.*, the Florida Antitrust Act, Fla. Stat. § 542.15, *et seq.*; the Missouri Merchandising Practices Act (“MMPA”), Mo. Rev. Stat. § 407.010, *et seq.*, the Missouri Antitrust Act, Mo. Rev. Stat. § 416.011, *et seq.*; New York General Business Law §§ 340 *et seq.*; and the Wisconsin Antitrust Act, Wis. Stat. § 133.03, *et seq.* Because Plaintiffs are “indirect purchasers,” they cannot bring a claim for damages for a violation of the federal antitrust laws. *See Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977) (indirect purchasers of goods cannot recover damages from antitrust violators under federal law).

- First, Plaintiffs have not alleged facts establishing that Shire engaged in “sham” patent litigation. The *Noerr-Pennington* Doctrine recognizes that the assertion of patent litigation claims is a fundamental right protected under the First Amendment because it is a form of petitioning the government. It further dictates that a party asserting patent litigation claims cannot be subject to antitrust liability unless those claims were a sham—that is, they were objectively baseless and caused injury to the plaintiff. Here, Plaintiffs cannot show either. Shire asserted three patents held on Intuniv against the generics after it received a Paragraph IV notice from them (a statutory act of infringement). While Plaintiffs criticize Shire’s assertion of one of those patents—the ‘290 patent—they do not challenge the validity of Shire’s claims with respect to the other two patents. Therefore, Plaintiffs cannot show that Shire’s infringement litigation (i) was objectively baseless, or (ii) in anyway delayed generic entry or otherwise caused them injury.
- Second, Plaintiffs cannot allege facts establishing that Shire’s patent litigation settlements with either Actavis or TWi/Anchen were anticompetitive “reverse payment” agreements. As the Supreme Court held in *Federal Trade Commission v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), an anticompetitive “reverse payment” occurs when there is a “large, unexplained” transfer of value from the branded manufacturer to the generic manufacturer as part of a patent litigation settlement. Here, Shire granted Actavis a license to sell generic Intuniv, and, in exchange, Actavis agreed to pay Shire a 25% royalty. While Plaintiffs allege that the 25% royalty was “below market,” the royalty payment plainly was not a payment in “reverse.” Moreover, as the Supreme Court recognized in *Actavis*, the grant of a

license in exchange for a royalty payment is not unlawful; indeed, it is a common and universally recognized method for resolving patent infringement claims.

Plaintiffs further allege that under the terms of its settlement agreement with Actavis, Shire agreed not to launch an Intuniv authorized generic (“AG”)⁴ product during the first 180 days of Actavis’s license and that Shire’s forbearance was another form of reverse payment. That allegation, however, is demonstrably false. In plain and unambiguous terms, the Actavis License Agreement (which Shire provided to Plaintiffs) states that Shire retained the right to market an AG product. Plaintiffs’ reverse payment claims are also deficient because they do not allege sufficient facts to quantify the amount of the “reverse payments” from Shire to Actavis. Consequently, they have not alleged that any payment was large and unexplained, an essential element of their claims.

- Third, Plaintiffs claims with regard to the TWi/Anchen settlement, suffer from many of the same infirmities. Like the Actavis settlement, Shire granted TWi/Anchen a license in exchange for a royalty payment. That is not a reverse payment, much less one that was either large or unexplained. In addition, Shire agreed to supply authorized generic Intuniv to TWi/Anchen under certain circumstances. Far from being anticompetitive, the authorized generic provisions would have allowed TWi/Anchen to introduce generic product into the market *before* they received regulatory approval to do so. Finally, the Plaintiffs suffered

⁴ An “AG” is a generic, unbranded version of the branded manufacturer’s product that the branded manufacturer makes and sells either to wholesalers or to third party distributor for resale. A “no-AG” agreement is an agreement by the brand company not to market or sell an AG.

no injury from the TWi/Anchen settlement because the settlement caused no delay in the launch of any generic Intuniv product.

- Fourth, both Plaintiffs’ Sherman Act-based claims and their stand-alone claims that Shire engaged in “unfair” or “deceptive” conduct in violation of state law also fail to state a claim for several additional reasons:
 - None of the Plaintiffs is a resident of Massachusetts, and under Massachusetts choice of law principles, the law of Massachusetts cannot apply.
 - Neither the Florida Antitrust Act nor Missouri law permits indirect purchasers to assert antitrust claims for damages. Accordingly, Plaintiff Richard has no right of action under the Florida Antitrust Act and Plaintiff Wright has no right of action at all.
 - Plaintiffs have not alleged facts sufficient to establish standalone liability for “unfair” or “deceptive” conduct under the laws of Massachusetts, Florida, Missouri, Wisconsin, or New York.

5. Plaintiffs’ Complaint therefore does not state a claim and should be dismissed. And it should be dismissed with prejudice, because nearly two months ago (and a month before Plaintiffs filed their Complaint) Shire provided the at-issue settlement agreements and other relevant documents to Plaintiffs. Nonetheless, Plaintiffs chose to ignore the information and continue to base their allegations “upon information and belief.” Having received the relevant agreements that they challenged in their original complaints, Plaintiffs should not be given another opportunity to amend and attempt to plead viable causes of action.

WHEREFORE, Shire respectfully requests that this Honorable Court:

- A. Dismiss the Complaint with prejudice; and
- B. Grant such additional or alternative relief as is deemed appropriate.

Respectfully submitted,

/s/ Joshua S. Barlow

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LOCAL RULE 7.1 CONFERENCE

I, Joshua S. Barlow, hereby certify that counsel for the Shire Defendants conferred in good faith with counsel for the Indirect Purchaser Plaintiffs and the putative class in an effort to narrow or obviate the need for this Motion by, *inter alia*, voluntarily producing documents referenced herein that the Shire Defendants believe undermine the merits of the Indirect Purchaser Plaintiffs' claims.

/s/ Joshua S. Barlow

Joshua S. Barlow

CERTIFICATE OF SERVICE

I, Joshua S. Barlow, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on this 10th day of April 2017.

/s/ Joshua S. Barlow

Joshua S. Barlow